FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
November 9, 2012

AGENDA

The committee will discuss data submitted by MSD Consumer Care, Inc. to support new drug application (NDA) 202211, for the partial switch from prescription to over-the-counter (OTC) of the oxybutynin transdermal system (proposed trade name OXYTROL FOR WOMEN). The proposed OTC use is "treats overactive bladder in women." The data to be discussed will include a summary of the postmarketing experience with the oxybutynin transdermal system, and the results of consumer studies, including label comprehension studies, self-selection studies, and an actual use study. The committee will be asked to consider whether the data support the appropriate and safe use of oxybutynin transdermal system by OTC consumers.

8:00 a.m.	Call to Order and Introduction of Committee	**Marcus Reidenberg, MD, FACP** Acting Chairperson, NDAC
8:05 a.m.	Conflict of Interest Statement	**Minh Doan, PharmD** Acting Designated Federal Officer, NDAC
8:10 a.m.	NDAC Member Appreciation and FDA Introductory Remarks	**Andrea Leonard-Segal, MD, MS** Director Division of Nonprescription Clinical Evaluation (DNCE) Office of Drug Evaluation IV (ODE IV) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**SPONSOR PRESENTATIONS**	
	Introduction	**Edwin Hemwall, PhD** R&D Leader, Rx-to-OTC Switch Merck Consumer Care
	Clinical Overview of Oxytrol	**Rajesh Mishra, MD, PhD** Head, Medical Affairs Merck Consumer Care
	Label Comprehension and Self-Selection Studies	**Stephen Neumann, MA** Head, Consumer Research Merck Consumer Care
	Actual Use Study: CONTROL	**Amy Replogle, MS** Program Leader, Rx-to-OTC Switch Merck Consumer Care
	Oxytrol for OAB in an OTC Setting	**Eman Elkadry, MD** Harvard Medical School Fellowship Director and Attending Physician Mount Auburn Hospital, Cambridge, MA

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AGENDA (cont.)

	SPONSOR PRESENTATIONS (CONT.)	
	Consumer Education & Support	**Kristie Licata, MBA** Product Development Leader, Rx-to-OTC Switch Merck Consumer Care
	Summary	**Edwin Hemwall, PhD**
9:40 a.m.	Clarifying Questions	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Overview of the Efficacy and Safety Database for NDA 21-351	**Donald McNellis, MD** Medical Officer Division of Reproductive and Urologic Products Office of Drug Evaluation III (ODE III) OND, CDER, FDA
	Oxytrol for Women® Label Comprehension and Self Selection Consumer Research	**Barbara Cohen, MPA** Social Science Analyst DNCE, ODE IV, OND, CDER, FDA
	Oxytrol for Women® – The Clinical Perspective	**Ryan Raffaelli, MD** Medical Reviewer DNCE, ODE IV, OND, CDER, FDA
11:35 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	